ARTICLE 19

AMENDED CLAIMS
received by the International Bureau on 18 July 2005 :
amended claims 1 to 4 replace original claims 1 to 4.

CLAIMS

1. A method of preparation of an oral solid dosage form with instant release of an active agent containing as the active agent finasteride characterized in that that an aqueous suspension containing 5% to 50% by weight of finasteride, based on the total weight of the suspension, and 0.1% to 50% by weight of at least one anion surfactant, based on the weight of finasteride, is milled in order to reach such distribution of particle size of finasteride form that the size of 10 % of particles does not exceed 2 μm, the size of 50% of particles does not exceed 7 μm, and the size of 90 % of particles does not exceed 17 μm, then the obtained aqueous suspension is sprayed in a fluid bed onto a solid particle hydrophilic carrier having such distribution of particle size that the size of 90 % of particles exceeds 40 μm and the size of 10 % of particles exceeds 200 μm, and the size of 99% of particles does not exceed 300 μm.

2. The method according to Claim 1 characterized in that that at least one substance of the following: sodium sulfosuccinate, sodium lauryl sulfate, sodium hexadecylsulfate, sodium hexadecylsulfonate, and sodium dioctylsulfosuccinate is used as anion surfactant.

3. The method according to Claim 1 or Claim 2 characterized in that that a hydrophilic sugar, as sucrose, sorbitol, mannitol, glucose and lactose, native or modified starch and cellulose or their mixtures, particularly a mixture of lactose, microcrystalline cellulose and modified maize starch at the weight ratio of 142 : 86 : 11 are used as the solid particle hydrophilic carrier.

4. The method according to whichever of the Claims 1 through 3 characterized in that that a mixture obtained by the spraying of the aqueous suspension onto the solid particle hydrophilic carrier in the fluid bed is mixed with 2 to 10 % by weight, based on the total weight of the obtained mixtur, of at least one pharmaceutically acceptable hydrophilic lubricant showing an antistatic effect, such as colloidal silicon dioxide, sodium stearyl fumarate, polyethylene glycol or sodium lauryl sulfate.

5. The method according to whichever of the Claims 1 through 4 characterized in that that the mixture obtained by the spraing of the aqueous suspension onto the solid particle hydrophilic carrier in the fluid bed is mixed with 1 to 7 % by weight, based on the total weight of the obtained mixture, of at least one pharmaceutically acceptable disintegrant, such as ultraamylopectin, cross-linked sodium carboxymethylcellulose or cross-linked polyvinylpyrrolidone.

6. The method according to whichever of the Claims 1 through 5 characterized in that that the mixture obtained by the spraying of the aqueous suspension onto the solid particle hydrophilic carrier in the fluid bed, optionally after being mixed with at least one lubricant and/or with at least one disintegrant, is filled into capsules or sachets or is pressed into tablets.

7. The method according to Claims 6 characterized in that that the tablets are coated with a water-soluble film or pigmented coating dispersion, particularly the dispersion of the hydrophilic coating mixture based on hydroxypropylmethylcellulose and hydroxypropylcellulose wherein the coat weight is 1 to 6 % by weight based on the weight of the uncoated tablet.